

REMARKS***Generally***

Claims 1-13 were pending in the application. Claims 7, 12, and 13 stand rejected under 35 USC §112. Claims 1-3 stand rejected under 35 USC §102 as being anticipated by Khan *et al.* (FEMS Microbiology Letters, Vol. 206, pages 209-214, January 10th, 2002) – hereinafter “KHAN.” Claim 4 stands rejected under 25 USC §102 as being anticipated by Person (US Publication # 2002/0072862) – hereinafter “PERSON.” Claims 5 and 8-11 stand rejected under 35 USC §102(a) as being anticipated by Xu *et al.* (Bioinformatics, vol. 18, pages 1432-1437, November 1st, 2002) – hereinafter “XU.” Claim 6 stands rejected under 35 USC §103(a) as being unpatentable over XU.

Claims 1-4 are canceled with this Reply. Claims 7, 12, and 13 are amended to overcome rejection under 35 USC §112. This Reply asserts that XU does not disclose the elements claimed in Claims 5-6 and 8-11. The application has been amended to address all pending objections.

Regarding Sequence Rules Compliance

Accompanying this Reply, please find a CD-ROM disc in duplicate containing a sequence listing pursuant to 37 C.F.R. 1.52(e)(1). Pursuant to 37 C.F.R. 1.52(e)(4), the two replacement CD-ROM discs are labeled “COPY 1 of 2” and “COPY 2 of 2”, respectively, and they are identical. Further, pursuant to 37 C.F.R. 1.52(e)(4), the CD-ROM discs contain no new matter. These data files are in ASCII format using the Windows XP operating system and were created on October 12, 2006. The data file contained on each copy is as follows with size listed parenthetically: SEQUENCE LISTING.txt (4,015 KB).

Regarding Priority

The OA asserts:

The instant specification appears to claim benefit from a prior application ... but the serial number of the application filed on 01/23/04 is left blank. The current status of all

non-provisional parent applications referenced should also be included.

The specification, as originally filed, contains a statement appearing in the first sentence claiming priority to U.S. Provisional Patent Application No. 60/441,806 filed January 23, 2003. All other cross references to related applications have been deleted from the specification.

Regarding the Specification and Abstract

The specification has been amended to delete incorporation by reference of the utility application filed 01/23/2004.

The OA objects to the blank contract number in the *Statement Regarding Federally Sponsored Research and Development*. An investigation is currently underway to identify contract(s), if any, in the performance of which embodiments of the invention were conceived or first reduced to practice. A reference to any such contract will be added to the application promptly upon identification. The undersigned proposes that this objection be held in abeyance until allowable subject matter is indicated.

The OA objects to the title of the application as not descriptive. The title has been amended to be clearly indicative of the invention to which the amended claims are directed. *Identification and Use of Informative Genetic Sequences* is clearly indicative of claims directed to identification and use of genetic sequences that, being unique to a set of organisms (and in some cases being amenable to hybridization in a fashion that is repeatable and distinguishable), are informative of the presence of such sets. The amendment increases the degree to which the title has value in indexing, classifying, searching, etc.; as called for by Manual of Patent Examining Procedure ("MPEP") §606.

The OA objects to the format of the Abstract as not properly formulated into a series of sentences. The Abstract has been amended so as to be formulated into a series of sentences.

The OA objects to the manner of reference to the trademarks TAQMAN® and GENBANK®. The specification has been amended to refer to these terms in a manner consistent with MPEP §608.01(v).

The OA objects to the use of an embedded hyperlink and/or other form of browser-executable code. The three (3) instances where hyperlink text was provided in the specification have been deleted.

The Specification has also been modified to make reference to the Sequence Listing on CD-ROM accompanying this Reply.

Given the number and dispersion of the amendments, a substitute specification is provided herewith. The substitute specification includes no new matter and is submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of added subject matter is by underlining the added text. The text of deleted matter is shown by strike-through. An accompanying clean version (without markings) is also supplied.

Regarding Claim Rejections – 35 USC §112

The OA asserts that dependent Claim 7 includes insufficient antecedent basis for the term *selected database* where the parent claim refers to both a ***first selected genomic database*** and a ***second selected genomic database***. Claim 7 has been amended to refer to ***each of the first and second selected databases***.

The OA asserts that Claims 12 and 13 omit:

... step(s) which indicate the relatedness of the search of genomic data characteristic of a first set of organisms to the inference of unique sequences in a second set of organisms.

Claims 12 and 13 have been amended to relate the search directed to the first set of organisms (i.e., the *set of organisms under investigation*) to search results unique a second set(s) (i.e., *at least one set of organisms other than the set of organisms under investigation*).

For these reasons, the undersigned requests that the rejections against Claims 7, 12, and 13 be withdrawn.

Regarding Claim Rejection of Claims 1-4 Under 35 USC §102(a)

Claims 1-4 have been canceled.

Regarding Claim Rejection of Claims 5 and 8-11 Under 35 USC §102(a) as Being Anticipated by XU

Claim 5 requires two searches against a genomic database(s) using a similarity search engine(s).

first searching a first selected genomic database using the query-length sequence and the first similarity search engine

second searching a second selected genomic database using the formatted target oligonucleotide sequences and the second similarity search engine

The OA asserts, at P09 L09-20, that XU discloses performing two searches against genomic databases (**bold emphasis added**):

They search query sequences with a first homology search engine, "PRIMEGENES first carries out the heuristic BLAST search for each ORF (query) against all other ORFs to quickly identify possible homologous sequences," (page 1433, 1st column, 2nd paragraph, lines 4-7).

Furthermore they carry out a second homology search with their target oligonucleotide sequences, "to further ensure that the primer will not amplify multiple sequences, gapless sequence **alignments are carried out** between the two primers and all the ORFs," (page 1433, 1st column, 2nd paragraph, lines 19-22).

While mere alignment can be one aspect of a similarity search engine, both the present application and XU distinguish between a similarity search engine (such as BLAST) and mere alignment. XU's "alignment" does not disclose searching a second genomic database using a similarity search engine. For at least this reason, the undersigned requests that the rejection against Claims 5 and 8-11 be withdrawn.

Regarding Claim Rejection of Claim 6 Under 35 USC §103

Claim 6, as dependent on Claim 5, requires two searches against a genomic database(s) using a similarity search engine(s). Claim 6 further specifies BLAST as the similarity search engine.

The OA implies that XU's mere "alignment" is a similarity search engine. As noted above with respect to Claims 5 and 8-11, this is not the case. For at least this reason, the undersigned requests that the rejection against Claim 6 be withdrawn.

CONCLUSION

The foregoing is submitted as a full and complete response to the OA mailed 07/12/2006 . With consideration of the above amendments and remarks directed to the rejections, the undersigned submits that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that the prosecution might be advanced by discussing the application with the undersigned, in person or over the telephone, we would welcome the opportunity to do so. No new matter has been added to the disclosure. An examination on the merits at your earliest convenience is respectfully requested. Please contact undersigned with any questions that will expedite prosecution.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1458, and please credit any excess fees to such deposit account.

Date: October 12, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'M. J. Dimino', is written over a horizontal line.

Michael J. Dimino
Registration No. 44,657

KILPATRICK STOCKTON LLP
607 14th St., N.W., Suite 900
Washington, D.C. 20005
(202) 508-5883